

## Coronavirus Disease 2019 (COVID-19)

CDC



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## Frequently Asked Questions about Laboratory Biosafety and SARS-CoV-2

Revisions were made on March 19, 2020, to reflect updated guidance.

### Specimen Handling

#### Q: How should the laboratory perform a risk assessment to identify and mitigate risks?

A: All laboratories should perform a site-specific and activity-specific risk assessment to identify and mitigate risks and determine if enhanced biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols. Risk assessments and mitigation measures are dependent on the procedures performed, identification of the hazards involved in the process and/or procedures, the competency level of the personnel who perform the procedures, the laboratory equipment and facility, and the resources available.

The risk assessment should identify all potential scenarios of a particular activity that could produce a negative outcome. The risk assessment should prioritize those potential negative outcomes, or risks, based on an evaluation of the likelihood and consequences of each of those identified risks. The risk assessment should determine the most appropriate control measures, and how the system will measure the effectiveness of those control measures.

For additional information, refer to the following:

- [Laboratory biosafety guidance related to the novel coronavirus \(2019-nCoV\)](#) 
- [Risk Assessment Best Practices](#) 
- [World Health Organization Laboratory Biosafety Manual, 3rd](#) 

#### Q: Are certified Class II biological safety cabinets (BSCs) required to process suspected or confirmed SARS-CoV-2 specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified Class II BSC?

A: For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Type A1 or A2 BSC or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

For additional information, refer to the following:

- [CDC 2019-Novel Coronavirus \(2019-nCoV\) Real-Time RT-PCR Diagnostic Panel](#) 
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
- [Laboratory biosafety guidance related to the novel coronavirus \(2019-nCoV\)](#) 

#### Q: How should point-of-care testing (POCT) be conducted outside a traditional laboratory?

A: For diagnostic testing of specimens conducted outside of a traditional clinical laboratory, such as rapid respiratory testing, use Standard Precautions to provide a barrier between the specimen and personnel during specimen manipulation.

For additional information, refer to:

- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

#### Q: If laboratory personnel collect blood or respiratory specimens directly from suspected or confirmed COVID-19 patients, what PPE should they wear?

If laboratory personnel have direct contact with suspected or confirmed COVID-19 patients, they should follow recommended PPE for health care providers while in the presence of these patients.

For additional information, refer to:

- [Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#)
- [OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard](#) 

#### Q: What is the recommended biosafety level for handling suspected or confirmed SARS-CoV-2 patient specimens?

A: Routine diagnostic testing of patient specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:

- Using automated instruments and analyzers
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Final packaging of specimens for transport to diagnostic laboratories for additional testing.

Specimens should already be in a sealed, decontaminated primary container

- Using inactivated specimens, such as specimens in nucleic acid extraction buffer
- Electron microscopic studies with glutaraldehyde-fixed grids

For additional information, refer to the following:

- [CDC 2019-Novel Coronavirus \(2019-nCoV\) Real-Time RT-PCR Diagnostic Panel](#) 
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
- [OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard](#) 

#### Q: What disinfectant should personnel use to decontaminate work surfaces?

A: Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 . Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

#### Q: How should specimens be stored?

A: Store specimens at 2-8oC for up to 72 hours after collection. If a delay occurs in extraction, store specimens at -70oC or lower. Store extracted nucleic acid samples at -70oC or lower.

For additional information, refer to the following:

- [Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#)
- [CDC 2019-Novel Coronavirus \(2019-nCoV\) Real-Time RT-PCR Diagnostic Panel](#) 

#### Q: How should laboratory personnel remove biohazardous waste from the laboratory or testing area for decontamination and disposal?

A: Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

For additional information, refer to the following:

- [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 5th edition](#)

#### Q: How should personnel transport suspected or confirmed SARS CoV-2 specimens within a facility?

A: Personnel should adhere to standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses, when they transport specimens within a facility. Personnel should perform site- and activity-specific risk assessments to determine if enhanced biosafety precautions are warranted based on situational needs.

For additional information, refer to the following:

- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
- [Laboratory biosafety guidance related to the novel coronavirus \(2019-nCoV\).pdf](#) 

#### Q: What are Standard Precautions?

A: Standard Precautions are based on the principle that all blood, body fluids, secretions, nonintact skin, mucous membranes, and excretions (except sweat) may contain transmissible infectious agents. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE) such as laboratory coats or gowns, gloves, and eye protection.

For additional information, refer to the following:

- [2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#) 
- [CDC Isolation Precautions](#)

#### Q: What are infectious aerosols and droplets?

A: **Aerosols and droplets** containing particles that are <100 µm in diameter are not visible to the naked eye. Laboratory workers may not be aware that such particles can be generated during many laboratory procedures and that these particles could be inhaled or could cross-contaminate work surfaces, materials, and equipment.

**Infectious aerosols** are small liquid or solid particles suspended in the air that contain infectious agents. They can disperse throughout the laboratory and remain infective over time and distance. These particles are of a size that may be inhaled into the lower respiratory tract (<5 µm in diameter). Examples of organisms transmitted by aerosols include spores of *Aspergillus* spp., *Mycobacterium tuberculosis*, *rubeola virus* (measles), and *varicella-zoster virus* (chickenpox).

**Droplets** traditionally are defined as larger infectious particles (>5 µm in diameter) that rapidly fall out of the air, contaminating gloves, the immediate work area, and the mucous membranes of the persons performing the procedure.

Examples of infectious agents that are transmitted via the droplet route include *Bordetella pertussis*, influenza viruses, adenovirus, *Mycoplasma pneumoniae*, SARS-associated coronavirus (SARS-CoV), group A streptococcus, and *Neisseria meningitidis*.

For additional information, refer to the following:

- [WHO Laboratory Biosafety Manual, 3rd](#) 
- [2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#) 
- [CDC Isolation Precautions](#)

#### Q: What procedures can generate aerosols and droplets?

A: Many routine laboratory procedures can potentially generate aerosols and droplets that are often undetectable. The following laboratory procedures have been associated with the generation of infectious aerosols and droplets: centrifugation, pipetting, vortexing, mixing, shaking, sonicating, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, subculturing blood culture bottles, spilling specimens, and cleaning up spills.

For additional information, refer to the following:

- [Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories](#) 
- [Biosafety in Microbiological and Biomedical Laboratories, 5th Ed.](#)
- [Laboratory biosafety guidance related to the novel coronavirus \(2019-nCoV\)](#) 

## Specimen Packing and Shipping

#### Q: Do people packing patient specimens, isolates or cultures for transport need to be trained and competent?

A: For transporting patient specimens, cultures or isolates, personnel must be trained in the proper safety, packing, and shipping regulations for Division 6.2, UN 3373 Biological Substance, Category B in accordance with the current edition of the [International Air Transport Association \(IATA\) Dangerous Goods Regulations \(DGR\)](#) . Personnel should be trained in a manner that corresponds to their function-specific responsibilities.

For additional information, refer to the following:

- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 
- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 

#### Q: What specific packaging should personnel use when shipping suspected or confirmed SARS-CoV-2 patient specimens, isolates or cultures?

A: A: Pack and ship suspected or confirmed SARS-CoV-2 patient specimens, cultures or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of the [International Air Transport Association \(IATA\) Dangerous Goods Regulations \(DGR\)](#) :

1. A leakproof primary container.
2. A leakproof, watertight secondary packaging with absorbent material.
3. A rigid outer packaging to protect the specimens during shipment.

For additional information, refer to the following:

- [IATA Dangerous Goods Regulations Packaging Instruction 650](#) 
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
- [Laboratory biosafety guidance related to the novel coronavirus \(2019-nCoV\)](#) 

#### Q: At what temperature should specimens be shipped?

A: Specimens should be shipped at 2-8oC with ice packs. If the specimen is frozen, ship overnight on dry ice. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the refrigerator used as well as the temperatures and the pressures which could result if refrigeration were lost. Packages containing dry ice should be designed and constructed so as to prevent the buildup of pressure and to allow the release of gas that could rupture the packaging.

For additional information, refer to the following:

- [CDC 2019-Novel Coronavirus \(2019-nCoV\) Real-Time RT-PCR Diagnostic Panel](#) 
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

#### Q: What information is required on the outer package for shipment of specimens with ice packs?

A: Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Name and phone number of a responsible person is optional if it is on the airway bill

For additional information, refer to the following:

- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 
- [Labels for UN 3373](#)
  - [When using cold pack](#)  – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- [Schematic for packaging, UN 3373, Category B](#) 

#### Q: What information is required on the outer packages for shipment of specimens with dry ice?

A: Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Hazard Labeled with UN Identification Number- UN 1845
4. Dry Ice along with the net weight (kg) of the dry ice
5. Shipper's name and address
6. Receiver's name and address
7. Name and phone number of a responsible person.

For additional information, refer to the following:

- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 
- [IATA Dangerous Goods Regulations Packaging Instruction 650](#)
  - [Packing Instructions 650 for UN 3373](#) 
  - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
  - [When using dry ice](#)  – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- [Schematic for packaging, UN 3373, Category B](#) 

#### Q: What information is required on an overpack if used for specimen shipment?

A: The overpack should be marked in accordance with the packing instructions required for the outer package:

1. Hazard labeled with UN Identification Number already on the label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Package Orientation Label
6. Marked with the word "Overpack"
7. Name and phone number of a responsible person is optional if it is on the airway bill

For additional information, refer to the following:

- [IATA Dangerous Goods Regulations Packaging Instruction 650](#) 
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

#### Q: Is a shipper's declaration required? What documentation is required for shipment? What if specimens are shipped on dry ice?

A: A shipper's declaration is not required for UN 3373 Biological Substance, Category B shipped samples. If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373 Biological Substance, Category B" along with the number of packages. If specimens are shipped on dry ice, include UN 1845, Dry Ice, 9, along with the net weight of the dry ice. See IATA PI 650 for additional information.

For additional information, refer to the following:

- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 
- [IATA Dangerous Goods Regulations Packaging Instruction 650](#) 

#### Q: Is a Responsible Person required on the shipping paperwork?

A: Yes, a Responsible Person should be listed on the air waybill or Shipper's Declaration (if applicable).

For additional information, refer to the following:

- [Guidance on regulations for the transport of infectious substances 2019 – 2020](#) 
- [IATA Dangerous Goods Regulations Packaging Instruction 650](#) 

#### Q: Once packaging of the samples is complete should staff members decontaminate the work area?

A: Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 . Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

For additional information, refer to the following:

- [Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#)
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

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